



DEPUTY SECRETARY OF DEFENSE
1010 DEFENSE PENTAGON
WASHINGTON, DC 20301-1010

AUG - 2 2001

Honorable Bob Stump
Chairman, Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515-6035

Dear Mr. Chairman:

Section 217 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001, Public Law No. 106-398, requires a written notification to Congress if total obligations exceed \$5.0 million in fiscal year (FY) 2001 funding in support of the procurement of a vaccine for the biological agent anthrax.

On July 20, 2001 the Department obligated \$10.5 million for this effort. Previously, on April 12, 2001, the Department reported to Congress FY01 obligations in the amount of \$16.9 million. The enclosed report provides justification for obligation of the funds. As you are aware, Anthrax Vaccine Adsorbed is a vital product for protecting our Service members against the lethal threat of anthrax and the Department remains firmly committed to providing a safe and effective vaccine that fully meets this critical requirement.

A similar letter and report have been provided to the President of the Senate, the Speaker of the House, the Chairman of the Senate Appropriations Committee, the Chairman of the Senate Appropriations Committee/Defense Subcommittee, the Chairman of the House Appropriations Committee, the Chairman of the House Appropriations Committee/ Defense Subcommittee, and the Chairman of the Senate Armed Services Committee.

Sincerely,

Enclosure:
Report on July 12, 2001 Fiscal Year 2001
Anthrax Vaccine Procurement Obligations

cc: Honorable Ike Skelton
Ranking Minority Member



Report on Fiscal Year 2001 Funds Obligated in Support of the Procurement of a Vaccine for the Biological Agent Anthrax

On July 12, 2001 the Department obligated \$10.5 million for efforts in support of the procurement of a vaccine for the biological agent anthrax. Previously, on April 12, 2001 the Department reported to Congress obligations in the amount of \$16.9 million. Total Fiscal Year 2001 obligations for this effort is \$27.4 million.

This report provides justification for the obligations summarized in the chart below, which relate to five activities. All five of the activities support actions that are necessary for the current manufacturer to comply with standards of the Food and Drug Administration (FDA), including those purposes necessary to obtain or maintain a biological license application, applicable to anthrax vaccine.

<u>Activity</u>	<u>Obligated</u>	<u>Contract</u>
<i>BioPort Process Validation:</i> Efforts to enable the contractor to meet FDA Biological License Application (BLA) requirements.	\$6.0M	DAMD1791-C-1139
<i>Warm Base:</i> The labor costs for BioPort employees to achieve current good manufacturing practices, pre-approval inspection, readiness, and protocol training efforts.	\$ 3.1M	DAMD1791-C-1139
<i>Redundancy:</i> Efforts to establish a redundant capability for performance of specific tasks which include Anthrax Vaccine Adsorbed (AVA) potency and lot release testing.	\$ 0.0M	DAMD1791-C-1139
<i>Testing and Storage:</i> AVA stability, sterility, storage, printing/packaging, shipping, and security.	\$ 0.4M	DAMD17-97-D-0003
<i>Contractor Oversight and In-House Support:</i> Monitoring and follow-up of BioPort's efforts to correct documented deficiencies and submit the BLA to the FDA. Provide program management support to the AVA program within the Joint Program Office for Biological Defense.	\$ 1.0M	DAMD17-01-D-0001
Total	\$10.5M	

July 12, 2001

Details of Efforts Related to Anthrax Vaccine Procurement: The Department of Defense's recent obligation of Fiscal Year 2001 funds for anthrax vaccine procurement is for five activities. All five of the activities support actions that are necessary for the current manufacturer to comply with standards of the Food and Drug Administration (FDA), including those purposes necessary to obtain or maintain a biological license application, applicable to anthrax vaccine. The activities are:

1. Process Validation:

DAMD1791-C-1139

\$6.0M

Process Validation is a series of steps, which includes retrospective validation, concurrent validation, prospective validation and revalidation. Retrospective Validation evaluates consistency and reproducibility through historical process details. Concurrent Validation examines and studies all process parameters including process "gap" parameters, not previously recorded or identified, as well as to conduct product characterization testing. Prospective Validation is conducted prior to the distribution of a product made under a revised manufacturing process, where the revision may affect product characteristics according to the pre-established validation plan. Revalidation repeats previous validation studies requiring regularly scheduled, ongoing validation of critical systems.

Steps involved in process validation include:

- Review Anthrax Vaccine Adsorbed (AVA) manufacturing process (batch records)
- Clarify process steps and stages
- Group process steps into process stages

Identified AVA process stages include seed expansion fermentation; production volume fermentation; Protective Antigen (PA) harvest; formulation of sublots; formation of final lots; and filling, labeling, packaging and release. Hollister-Stier has the contract to do the filling. With these stages defined, critical and non-critical parameters for each process stage can be defined, measurements reviewed, and existing protocols can be correlated to process steps.

These projects are designed to improve existing systems in order to satisfy Food and Drug Administration (FDA) requirements for approval of the supplemental Biological License Application.

2. Warm Base: **DAMD1791-C-1139** **\$ 3.1M**

Warm Base includes work on a wide range of activities needed to comply with FDA requirements. Activities include programming and maintenance of Information Technology (IT) capabilities; scientific research services related to AVA production; regulatory compliance; facilities and equipment upkeep; quality assurance auditing; employee training; retaining human resource skill bases; ensuring manufacturing capability; production area formulation; filling and packaging capability and administration; controlled room inventory management; and temperature monitoring.

3. Redundancy: **DAMD1791-C-1139** **\$ 0.0M**

Redundancy involves retesting Historical Potency Tests in an analogous fashion like BioPort has been conducting the testing, in an effort to reproduce the same results obtained by BioPort. This will be accomplished for the Pilot Potency Test, Plate Count Validation, LD₅₀ Comparison with multiple spore lots and multiple sources of guinea pigs, and Spore Count Validation. Battelle Memorial Institute has the contract to conduct this testing.

4. Testing and Storage: **DAMD17-97-D-0003** **\$ 0.4M**

AVA stability, sterility, and potency testing, storage, printing, packaging, shipping, and security.

5. Contractor Oversight: **DAMD17-01-D-0001** **\$ 1.0M**

Monitoring and follow-up of BioPort's efforts to correct documented deficiencies and submit the BLA to the FDA. Provide program management support to the AVA program within the Joint Program Office for Biological Defense. Camber Corporation, Quantic Corporation FTS, and Don Hill Associates provide contractor oversight. The Fiscal Year 2001 funds obligated under this contract modification were provided to Camber Corporation.

Total Fiscal Year 2001 Funding Obligated on July 12, 2001: **\$10.5M**